



JUL 25 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Ejaz Ahmed Chatha
Chief Executive
Instrumed (Pvt) Ltd.
65-B Small Industrial Estate
P.O. Box 615
Sialkot-51310, Pakistan

Dear Mr. Chatha:

During an inspection of your firm located in Sialkot, Pakistan on April 25, 1997, our investigator determined that your firm manufactures surgical and dental instruments. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection conducted at your facility revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with Title 21, Code of Federal Regulations (CFR) for Medical Devices regulation of 1978. The 1978 GMP regulation was superseded on June 1, 1997, by the Current Good Manufacturing Practice (CGMP) requirements as set forth in the Quality System Regulation, 21 CFR Part 820. The deficiencies noted during the inspection reference the 1978 GMP requirements, with a cross reference to the new 1997 Quality System Regulation.

1. Failure of the quality assurance program to consist of procedures adequate to assure the approval or rejection of all components, manufacturing materials, in-process materials, packaging materials, labeling, and finished devices; and failure to approve or reject devices that are manufactured, processed, packaged, or held under contract by another company, as required by 21 CFR 820.20(a)(2). This would also be a violation of the Quality System Regulation, 21 CFR 820.90 and 21 CFR 820.50. For example:

- a. There is no provision to handle in-process and finished device rejects.

Your response may be adequate. The response states that the Standard Operating Procedure (SOP) for Rejected Material/Devices describing the procedure for handling rejects from in-process and finished devices is revised. A copy of the SOP is enclosed with the response. We will verify the implementation of this procedure during our next inspection of your facility.

- b. There are no provisions in place to assure that the integrity of the finished ~~XXXXXXXXXX~~ device is maintained; that is, the identity of the device may be lost.

Your response is not adequate. There is no response in the June 2, 1997, letter for this deficiency.

2. Failure to implement planned and periodic audits of the quality assurance program to verify compliance with the quality assurance program, and to perform the audits in accordance with written procedures by appropriately trained individuals not having direct responsibilities for the matters being audited, as required by 21 CFR 820.20(b). This would also be a violation of the Quality System Regulation, 21 CFR 820.22. For example, there is no evidence that an audit of the quality assurance program has been performed.

Your response may be adequate. Your response states that an internal audit of the facility has been conducted since the inspection, and a copy of the internal audit log is enclosed with the response.

3. Failure to establish procedures for specification control measures to assure that the design basis for the device, components, and packaging is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). This would also be a violation of the Quality System Regulation, 21 CFR 820.75. For example, validation of the manufacturing processes has not been performed.

Your response may be adequate. Your response states that process validation has been performed on the ultrasonic cleaning and electro-polishing processes. Copies of the report are enclosed with the response. However, it is unclear whether other significant manufacturing processes have been validated. Please provide documentation to demonstrate that your manufacturing processes have been validated.

4. Failure to maintain a formal approval procedure for any change in the manufacturing process of a device, and to communicate any approved change to appropriate personnel in a timely manner, as required by 21 CFR 820.100(b)(3). This would also be a violation of the Quality System Regulation, 21 CFR 820.70(b). For example, there is no evidence of adequate change control procedures.

Your response may be adequate. Your response states that all changes are now made according to a change control procedure and that the SOP [REDACTED] has been amended. A copy of the complete SOP is enclosed with the response. We will verify the implementation of this procedure during our next inspection of your facility.

5. Failure to check and, where necessary, test each production run, lot or batch for conformance with device specifications prior to release for distribution, as required by 21 CFR 820.160. This would also be a violation of the Quality System Regulation, 21 CFR 820.80(d). For example, finished devices are not analyzed for any of the attributes of stainless steel content prior to release for distribution.

Your response may be adequate. Your response states that laboratory analyses for finished devices and incoming stainless steel began upon completion of the inspection. An analysis for one finished device is included with the response. We will verify the implementation of this process during our next inspection of your facility.

6. Failure to have written procedures for acceptance of components, and to maintain a record of component acceptance and rejection, as required by 21 CFR 820.80(a). This would also be a violation of the Quality System Regulation, 21 CFR 820.80(b). For example, there is no Certificate of Conformance or Certificate of Analysis provided with the stainless steel purchased from [REDACTED] nor is there any confirmation analysis performed on receipt.

Your response may be adequate. Your response states that analysis for the seven elements of stainless steel has started prior to approving the component for production. Laboratory analysis of the finished device has also begun. The SOP for Material/Product Acceptance/Release has been revised. A copy of a Certificate of Analysis, a laboratory analysis report, and the revised SOP are enclosed with the response. We will verify the implementation of this process during our next inspection of your facility.

7. Failure to review, evaluate, and maintain by a formally designated unit, written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device, as required by 21 CFR 820.198(a). This would also be a violation of the Quality System Regulation, 21 CFR 820.198(a). For example, there is not an adequate complaint handling system.

Page 4 - Mr. Ejaz Ahmed Chatha

Your response is adequate. Your response states that the SOP for complaints is revised to include a detailed complaint investigation report and all future complaints will be handled in accordance with this SOP. A copy of the revised SOP is enclosed with the response.

Additionally, the above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed to develop, maintain, and implement written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17. You also failed to establish and maintain MDR event files, as required by 21 CFR 803.18(a).

Your response may be adequate. Your response states that SOP "SOP for Complaints" includes provision for filing MDR with FDA. We will verify the implementation of this procedure during our next inspection of your facility.

Given the serious nature of these violations of the Act, all devices manufactured by Instrumed (Pvt) Ltd., 65-B Small Industrial Estate, P.O. Box 615, Sialkot -51310, Pakistan may continue to be detained upon entry into the United States (U.S.) without physical examination until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter on items 1(b) and 3 for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

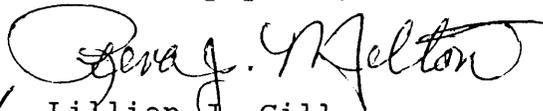
Please notify this office, in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved.

In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

Page 5 - Mr. Ejaz Ahmed Chatha

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Carol Shirk.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill". The signature is written in dark ink and is positioned above the typed name.

for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health